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	Title DoD Assurance		Page 1 of 3
	Process Owner Management Analyst CIP Department		Approval Authority Head, CIP Department

1. Purpose & Scope

This process defines the method of ensuring compliance with Federal policy regarding permission for engaging in human subject research. This process applies to all Naval medical and dental treatment facilities intending to engage in human subject research.

2. References

The following documents are either required or helpful to perform the set of tasks in the accompanying flowchart; a) NSHS-002, Quality Systems Document Control, b) NSHS-004 Corrective & Preventive Action, c) The Nuremberg Code, d) The Belmont Report "The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research", e) 32 CFR Part 219 "Federal Policy for the Protection of Human Subjects; Notices and Rules", f) DODD 3216.2 "Protection of Human Subjects in DOD-Supported Research", g) SECNAVINST 3900.39 "Protection of Human Subjects", h) NSHSBETHINST 6000.41 "Clinical Investigation Program" i) OSD MEMO OF 10 Jun 93 "Department of Defense (DOD) Guidance for Assurance of Compliance with the Federal Policy for the Protection of Human Subjects".

3. Definitions

The terms listed below are defined to assist the reader.

- 3.1 Clinical Investigation Department (CID) - Each CID will act as local or regional program manager for clinical investigations within its area of responsibility. The Commander/Commanding Officer of each medical treatment facility and dental treatment facility with a CID has responsibility for the implementation of his/her local program.
- 3.2 Clinical Investigation Program (CIP) - the system of directives, offices, and personnel that enable clinical research within the Department of the Navy.
- 3.3 Clinical Investigation Program Research - a research program, project, task, test, experiment, record review, evaluation, or similar undertaking that uses data collected from DoD health care beneficiaries, laboratory animals, or in vitro to study the maintenance of health or the prevention, alleviation or cure of disease, and whose primary purpose is designed with the intent to develop or contribute to generalized knowledge.

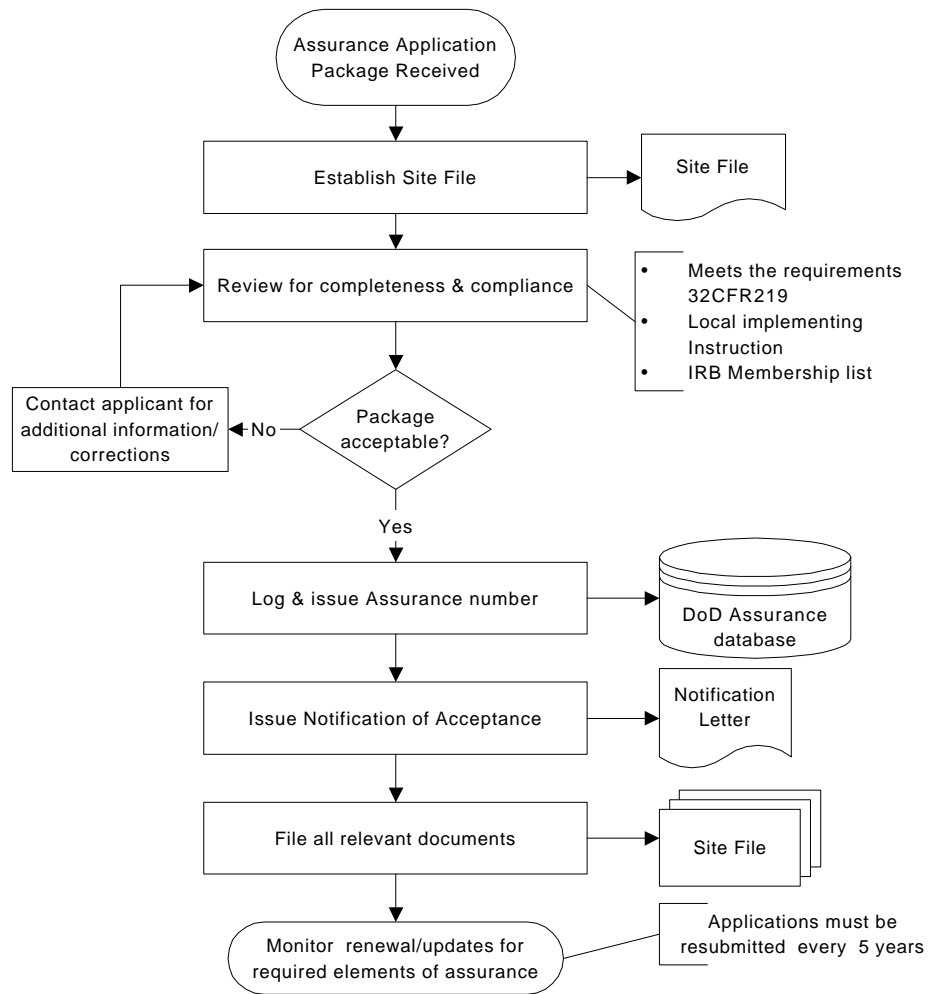
4. Document Review & Concurrence

Title of Reviewer	Functional Directorate	Signature & Date	Title of Reviewer	Functional Directorate	Signature & Date
Management Analyst CIP Department	OP6 (Process Owner)	Ms. E. Cooper	Head, CIP Department	OP6 (Approval Authority)	CAPT P. Kent

5. Summary of Changes

Version	Description	Date
01	Initial issue of procedure.	17 MAY 01

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6. Process Flowchart

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7. Quality Records

<i>Record Name</i>	<i>Owner</i>	<i>Location</i>	<i>Indexing</i>	<i>Duration</i>	<i>Disposition</i>
DoD Assurance Database	Management Analyst	Database	By Assurance number	Permanent	SECNAVINST 5212 series
Site File	Management Analyst	File Cabinet	By Site Name	Permanent	SECNAVINST 5212 series

8. Addendum

N/A